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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
CHU, YONG LIANG	
ART UNIT	**PAPER NUMBER**
1626	
MAIL DATE	**DELIVERY MODE**
10/16/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/552,595	MORAND ET AL.	
	Examiner	Art Unit	
	YONG CHU	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *47-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *47-57* is/are rejected.

7)☒ Claim(s) *53* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-46 have been cancelled by amendment filed 07/28/2008. Claims 47-57 are new by the amendment. Therefore, claims 47-57 are pending, and are under examination on the merits.

Response to Argument

Rejection of claims under 35 U.S.C.§102(b)

Applicant's arguments over rejection of claims 1, 3-4, and 6 under *35 U.S.C.§102(b*) is moot, because the claims have been canceled by Applicants.

Claim Objections Rejection of claims under 35 U.S.C.§102(b)

The objection is moot, because the claims have been cancelled by the amendment.

Examination of new claims 47-57

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 47-57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

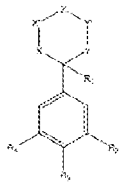
one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 47-57 are rejected due to claiming a prodrug of a compound of Formula (I). The instant specification defines prodrug of a compound of formula (I) at paragraph [0237] as broadest sense and encompasses those derivatives that are converted in vivo to the compounds of the invention. However, such derivatives would not readily occur to those skilled in the art. According to Wikipedia, prodrugs can be classified into two types based on their sites of conversion into the final active drug form: Type I, those that are converted intracellularly (e.g., anti-viral nucleoside analogs, lipid-lowering statins, antibody-directed/gene-directed enzyme prodrugs [ADEP/GDEP] for chemotherapy), and Type II, those that are converted extracellularly, especially in digestive fluids or the systemic circulation (e.g., etoposide phosphate, valganciclovir, fosamprenavir). Both types can be further categorized into subtype A or B, based on additional criteria. Those for the Type IA and IB are whether or not the cellular converting location is the site of therapeutic action. For the Type IIA and IIB, they are categorized depending on whether the conversion occurs in the gastrointestinal (GI) fluids or systemic circulation, Wu and Farrelly, Toxicology 236:1-6, 2007. However, such "prodrug" of the Formula (I) is not described in the specification to reasonably convey one skilled in the art. Therefore, the specification fails to comply with the written description requirement. To overcome the rejection, Applicants need to either delete the term "prodrug" from the claims or explain how to figure out the **broadest sense** and encompasses those derivatives of the prodrug that are converted in vivo to the compounds of the invention according to claim 47.

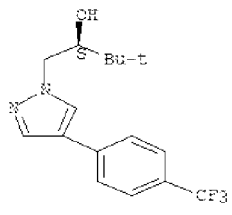
Claim Rejections - 35 USC § 102(b)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 47, 49, 51, and 56 are rejected under 35 U.S.C. 102 (b) as being anticipated by Barrett et al., *PCT publication WO2003-013518* ("the `518 publication").

Applicants' claims relate to a compound of formula (I)  according to claim 47 , wherein **Z** represents a covalent single bond between **X'** and **Y'**; **X** and **X'** taken together form –C($\mathbf{R_5}$)=N-; **Y'** is –N($\mathbf{R_5}$)-; and **Y** is –C($\mathbf{R_5}$)- and taken together with the carbon atom bearing the phenyl ring forms a double bond and $\mathbf{R_1}$ is absent; $\mathbf{R_2}$ and $\mathbf{R_4}$ are independently –H, or $C_{1\text{-}3}$alkyl; $\mathbf{R_3}$ is $C_{1\text{-}3}$alkyl and $(\mathbf{A})_\mathbf{m}\mathbf{R_{12}}$; -C($\mathbf{R_5}$)- is selected from –C(H)- and –C($C_{1\text{-}20}$alkyl)-; -N($\mathbf{R_5}$)- is selected from –N(H)- and –N($C_{2\text{-}20}$alkyl)-; and **m** is 0, or a pharmaceutical composition comprising said compound.

The `518 publication (published on 02/20/2003) disclose the compound (CAS RN 497946-99-3)  . This compound was disclosed <u>as an intermediate</u> in ***<u>Example 14b</u>*** of the specification, which reads on the instantly claimed scope of

invention wherein **Z** represents a covalent single bond between **X'** and **Y'**; **X** and **X'** taken together form –C(**R_5**)=N-; **Y'** is –N(**R_5**)-; and **Y** is –C(**R_5**)- and taken together with the carbon atom bearing the phenyl ring forms a double bond, wherein **R_2** and **R_4** are –H; **R_3** is C_{1-3}alkyl; and **R_5** is C_{2-20}alkyl. The **R_3** is defined as C_{1-3}alkyl, which may be optionally substituted with one ore more times by halo (e.g. Cl, F, or Br) according to the instant Specification at paragraph [0095], page 10, and can be $–CF_3$. The **R_5** is defined as C_{2-20}alkyl, which may be optionally substituted with one ore more times by -OH according to the instant Specification at paragraph [0095]. Therefore, the prior art compound anticipates the instant claims.

Claim Objections

Claim 53 is object to for an obvious error at the definition of -N(**R_5**) as "3-methylbutyl". It should be "-N(3-methylbutyl)". Appropriate correction is required.

Conclusion

- No claims are allowed.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Chu whose telephone number is 571-272-5759. The examiner can normally be reached between 7:00 am - 3:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571-272-0699. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Status Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Yong Chu, Ph.D./
Patent Examiner
Art Unit 1626